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FROM: James J. Mullen III, Ph.D. – Reg. No. 44,957 **DATE:** May 31, 2005

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Comments:

ATTORNEY DOCKET:	270142000300
GROUP ART UNIT:	1761
EXAMINER:	K. Hendricks
SERIAL NO.:	09/530,795
FILING DATE:	November 5, 1998 (Int'l)
INVENTOR(S):	Brian C. KELLER et al.
TITLE:	ENHANCED INFANT FORMULA CONTAINING LIPOSOME ENCAPSULATED NUTRIENTS AND AGENTS

Papers attached:

1. Transmittal (1 page)
2. Fee Transmittal (1 page + duplicate for fee processing)
3. Petition for Extension of Time (1 page)
4. Appeal Communication to TC – Appellant's Brief with Appendix A (7 pages)

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PTO/SB/21 (09-04)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/530,795
Filing Date	November 5, 1998 (Int'l)
First Named Inventor	Brian C. KELLER
Art Unit	1761
Examiner Name	K. Hendricks
Total Number of Pages in This Submission: 12	Attorney Docket Number: 270142000300

ENCLOSURES (*Check all that apply*)

- [x] Fee Transmittal Form (1 page + duplicate for fee processing)
- [ ] Fee Attached
- [ ] Amendment/Reply
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [x] Extension of Time Request (1 page)
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
- [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) ____
- [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) with Appendix A (7 pages)
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please identify below):

Facsimile coversheet (1 page)

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Firm Name	MORRISON & FOERSTER LLP		
Signature			
Printed name	James J. Mullen III, Ph.D.		
Date	May 31, 2005	Reg. No.	44,957

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Dated: May 31, 2005 Signature: (Grace L. Yu)

Docket No.: 270142000300
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Brian C. KELLER, et al.

Application No.: 09/530,795 Group Art Unit: 1761

Filed: November 5, 1998 (Int'l) Examiner: K. Hendricks

For: ENHANCED INFANT FORMULA CONTAINING LIPOSOME ENCAPSULATED NUTRIENTS AND AGENTS

APPELLANT'S BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This brief is filed in furtherance of the Notice of Appeal filed in this case on October 28, 2004, and is in furtherance of said Notice of Appeal. A petition for an extension of time of five (5) months until May 31, 2005 (May 28, 2004 being a Saturday, and May 30 being Memorial day) is attached along with the required fee.

The fees required under § 41.20(b)(2) and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

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This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is Biozone Laboratories, Inc. by virtue of the assignment recorded at reel/frame no. 012533/0995.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-14 were originally filed. Claims 1-14 were cancelled and new claims 15-23 were added by amendment on March 26, 2002. Claims 16-17 and 23 were cancelled and claim 24 was added by amendment on March 5, 2004. . Pending claims 15, 18-22 and 24 were finally rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking adequate written description, in the Office action mailed March 25, 2003. Claims 15, 18-22 and 24 were finally rejected under 35 U.S.C. . § 112, second paragraph for allegedly being indefinite. Applicants appeal the final rejection of the pending claims.

IV. STATUS OF AMENDMENTS

Applicant filed an Amendment After Final Rejection on October 28, 2004. The Examiner responded to the Amendment After Final Rejection in an Advisory Action mailed November 17, 2004. In the Advisory Action, the Examiner indicated that Applicants' proposed amendments to claims would not be entered.

Accordingly, the claims enclosed herein as Appendix A do not incorporate the amendments to claims, submitted in the response to the final Office Action on October 28, 2004.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention relates to formulations of infant milk formula that uses liposomes to deliver nutrients, stabilize ingredients and enhance the bioavailability of ingredients in the infant mile formula. Specification, page 4, line 29 to page 5, line 2. The invention exploits the use of liposomes in the making of infant nutritional formula that more accurately reflects the structures contained in natural mothers milk. The use of liposomes in infant nutritional formulations serves to increase the oral bioavailability of nutrients in the nutritional formulation. Specification, page 5, lines 18-25. The specification discloses the use of phospholipids in the liposomes from 0.1-50%. Specification, page 5, lines 6-7. Specific percentages of phospholipids are disclosed in the examples, such as 1.0% and 2.0%. Specification, Example 1, page 6 and Example 2, page 8.

VI. ISSUE

The sole issue on appeal is whether there is sufficient written description in the present application to support claim language reciting phospholipids in an amount between 1.0% and 2.0%.

VII. GROUPING OF CLAIMS

For purposes of this appeal brief only, and without conceding the teachings of any prior art reference, all of the claims are grouped into a single group. Thus, the pending claims stand or fall together.

VIII. ARGUMENTS

The present appeal addresses the single issue of whether the pending claims lack adequate written support. Specifically, Applicants have attempted to amend the claims to recite a liposome composition that comprises, *inter alia*, a phospholipid concentration from between 1.0% to 2.0%.[1] The Examiner has refused to enter this amendment because, in his view, there is no support in the specification for this limitation. The Examiner is in error.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991). The Federal Circuit in *Union Oil of California*, made it clear that an applicant need not precisely recite each and every element of a claim limitation in the specification in order to satisfy the written description requirement. *See Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000).

The facts of the present case are reminiscent of the facts in *In re Wertheim*, 541 F.2d 257 (CCPA 1976). In *In re Wertheim*, applicants recited a range in the specification from 25-60% solid content along with specific embodiments at 36% and 50%. *Id.* at 265. The CCPA held that, "as a factual matter, persons skilled in the art would consider processes employing a 35-60% solids content to be part of appellant's invention . . . ." *Id.* The court made this finding even though there was no explicit support for the particular range claimed, only for specific embodiments of 36% and 50%.

In the present case, the specification discloses formulas with a lipid concentration range from 0.1-50%. Specification at page 5, lines 3-10. The examples recite particular embodiments that contain 1.0% phospholipids (Example 1, formulas 1 and 2) and 2.0% phospholipid (Examples 2, 3 and 4). Thus, just as in *In re Wertheim*, literal support for these and other range boundaries can be literally derived from the specification as filed.

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[1] Applicants attempted to reintroduce the term "phospholipid" in the claims as part of the amendments made in response to the final Office Action. These amendments were not entered. Applicants note that the term "phospholipids" was recited in the claims prior to the amendment submitted on March 5, 2004.

The Office acknowledged in the last action the disclosure noted above. However, the Office persists in the notion that while in order for a range in a claim to be adequately supported, that range must be explicitly disclosed. As the discussion in *In re Wertheim* illustrates, this position of the Office is in error and should be withdrawn.

> "The PTO has done nothing more than to argue lack of literal support, which is not enough. If lack of . If lack of literal support alone were enough to support a rejection under § 112, then the statement of *In re Lukach,* [citation omitted] that 'the invention claimed does not have to be described in ipsis verbis in order to satisfy the description requirement of § 112,' is empty verbiage. The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in ipsis verbis is insufficient. *Id.*

Applicants urge the Board to overturn the Examiner regarding the sole issue on appeal. The Examiner has failed to provide any sound reasons why one of ordinary skill in the art would not reasonably conclude that the range of between 1.0% and 2.0% is not adequately supported. As discussed in *In re Wertheim,* the issue the Board must decide is:

> [W]hether the invention appellants seek to protect by their claims is part of the invention that appellants have described as theirs in the specification. That what appellants claim as patentable to them is less than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. . . . To rule otherwise would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed.

In light of the disclosure that explicitly provides teachings with phospholipid concentrations is the claimed range, to uphold the Examiner's position in this case would let a perceived requirement for literal disclosure of a range of phospholipids to triumph over the substance of the invention disclosed by Applicants. Accordingly, Applicants request that the Board reverse the Examiner's position regarding the claimed range and direct that the Examiner prosecute the claims with this range of phospholipids.

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IX. CLAIMS INVOLVED IN THE APPEAL

The Appendix contains a copy of the claims on appeal.

X. CONCLUSION

All of the claims pending are directed to a liposome preparation comprising a natural bilayer-forming lipid component consisting of a phospholipids concentration between 1.0% and 2.0% and an active ingredient comprising one or more components selected from the group consisting of micronutrients, proteins, immunoglobulins, vitamins and minerals. The Examiner has erred by not permitting Applicants to amend the pending claims to the stated concentration of phospholipids. This limitation is fully supported by the present specification. Thus, claims 15, 18-22 and 24 are in condition for allowance and passage of these claims to issuance is respectfully requested.

Dated: May 31, 2005

Respectfully submitted,

By _____

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 09/530,795

1-14. (canceled)

15. A liposome preparation consisting essentially of a natural bilayer-forming lipid component and an active ingredient component,

wherein the lipid component consists of a bilayer forming lipid concentration of between 0.2% to 2.0% (w/w) of the liposome preparation, and

wherein the active ingredient component comprises one or more components selected from the group consisting of micronutrients, proteins, immunoglobulins, vitamins and minerals.

16-17. (canceled)

18. The liposome preparation of claim 15, wherein the lipid component is selected from the group consisting of glycerolphospholipids, sphingophospholipids, and mixtures thereof.

19. The liposome preparation of claim 15, wherein the lipid component is selected from the group consisting of glyceroglycolipids, sphingoglycolipids, and mixtures thereof.

20. The liposome preparation of claim 15, further comprising a stabilizer, wherein the stabilizer is selected from the group consisting of cholesterol, stigmasterol, carrageenan, and mixtures thereof.

21. The liposome preparation of claim 20, wherein the concentration of the stabilizer comprises 0.05% to 30% w/w of the liposome preparation.

22. The liposome preparation of claim 15, wherein the micronutrients consist of thiamine HCl and ferrous sulfate.

23. (canceled)

24. The liposome preparation of claim 15 that is useful in a nutritional supplement or an infant formula.

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